

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: **Daniel J. DRUCKER**
Title: *Glucagon-Like Peptide-2 and its Therapeutic Use*
Appl. No.: **Not Yet Assigned**
Filing Date: **November 20, 2002**
Prior App. No.: **08/632,533**
Prior Filing Date: **April 12, 1996**
Examiner: **Not Yet Assigned**
Art Unit: **Not Yet Assigned**

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PRELIMINARY AMENDMENT

Commissioner for Patents
Box PATENT APPLICATION
Washington, D.C. 20231

Sir:

Prior to examination of the present application, Applicants respectfully request that the application be amended as follows:

In the Specification:

After the Application Title and before the first line of application text, insert the following paragraph:

--This application is a continuation of Application Serial No. 08/632,533, filed April 12, 1996, which is a continuation-in-part of Application Serial No. 08/422,540, now U.S. Patent No. 5,990,077, filed April 14, 1995.--

In the Claims:

Please cancel claims 1-17 without prejudice or disclaimer. Applicants reserve the right to file one or more continuing applications directed to their subject matter.

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OFFICE OF PETITIONS

Please add the following new claims:

--18. A method for improving the function of gastrointestinal tissue in a patient in need thereof, comprising the step of administering to the patient an effective amount of a pharmaceutical composition comprising GLP-2 to enhance the nutritional absorption of the small intestine.

19. A method for improving the function of gastrointestinal tissue in a patient in need thereof, comprising the step of administering to the patient an effective amount of a pharmaceutical composition to enhance the nutritional absorption of the small intestine, wherein said pharmaceutical composition comprises a GLP-2, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier, which has the formula (SEQ ID NO. 1):

R1-(Y)m-His-Ala-Asp-Gly-Ser-Phe-Ser-Asp-Glu-Met-Asn-Thr-aa1-Leu-Asp-aa2-Leu-Ala-aa3-aa4-Asp-Phe-Ile-Asn-Trp-Lcu-aa5-aa6-Thr-Lys-Ile-Thr-Asp-(X) n-R2

wherein:

aa1 is Met, Leu, Ile, Val or Cys;

aa2 is Ala, Ser, Thr, Pro, Gly, Asn, Asp, Glu or Gln;

aa3 is Ala, Ser, Thr, Pro or Gly;

aa4 is His or Arg;

aa5 is Met, Leu, Ile, Val or Cys;

aa6 is Asn, Asp, Glu, Gln, His, Arg or Lys;

X is His, Arg, Lys, His-His, His-Arg, His-Lys, Arg-His, Arg-Lys, Lys-His, or Lys-Lys;

Y is one or two amino acids selected from the group consisting of His, Arg and Lys;

m is 0 or 1;

n is 0 or 1;

R1 is H or an N-terminal blocking group; and

R2 is OH or a C-terminal blocking group, wherein the GLP-2 or salt thereof is comprised of a naturally occurring GLP-2, and when aa1 is Ile, aa2 is Asn, aa3 is Ala, aa4 is Arg, aa5 is Ile, aa6 is Gln, and n is 1, then X is not Arg.

20. A method for improving the function of gastrointestinal tissue in a patient in need thereof, comprising the step of administering to the patient an effective amount of a pharmaceutical composition to enhance the nutritional absorption of the small intestine, wherein said pharmaceutical composition comprises a pharmaceutically acceptable salt of GLP-2, and a pharmaceutically acceptable carrier wherein the GLP-2 has the amino acid sequence (SEQ ID NO. 2):

R1 - (Y)m-His-Ala-Asp-Gly-Ser-Phe-Ser-Asp-Glu-Met-Asn-Thr-Ile-Leu-Asp-Asn-Leu-Ala-aa3-Arg-Asp-Phe-Ile-Asn-Trp-Leu-Ile-Gin-Thr-Lys-Ile-Thr-Asp- (X) n-R2

wherein:

aa3 is Ala, Ser, Thr, Pro or Gly;

X is His, Arg, Lys, His-His, His-Arg, His-Lys, Arg-His, Arg-Lys, Lys-His, or Lys-Lys;

Y is one or two amino acids selected from the group consisting of His, Arg and Lys;

m is 0 or 1;

n is 0 or 1;

R1 is H or an N-terminal blocking group;

R2 is OH or a C-terminal blocking group; and

when aa3 is Ala and n is 1, then X is not Arg.

21. A method for enhancing the nutritional absorption of the small intestine in a patient in need thereof, comprising the step of administering to the patient an effective amount of a pharmaceutical composition comprising a vertebrate 33 amino acid GLP-2 or an analog thereof, which vertebrate GLP-2 or analog thereof has intestinotrophic activity, and wherein said analog is structurally altered relative to such vertebrate GLP-2 by at least one amino acid addition, deletion, substitution or by incorporation of an amino acid blocking group to enhance the nutritional absorption of the small intestine.

22. The method according to claim 21, wherein the GLP-2 peptide is vertebrate GLP-2.

23. The method according to claim 22, wherein the GLP-2 peptide is human GLP-2.

24. The method according to claim 21, wherein said GLP-2 peptide is an analog of vertebrate 33 amino acid GLP-2.

25. (New) The method according to claim 24, wherein said analog is an analog of human GLP-2.

26. (New) The method according to claim 25, wherein said pharmaceutical composition is suitable for administration by injection.--

REMARKS

Applicant respectfully requests that the foregoing amendments be made prior to examination of the present application.

After amending the claims as set forth above, claims 18-26 are now pending in this application. Claims 18-26 correspond to allowed claims 30, 31, 32, 47 and 65-68, respectively, of the parent application, U.S. Serial No. 08/632,533 that has been withdrawn from issue and expressly abandoned in favor of the present application. Exemplary support for claim 18 is found on page 18, lines 18-21. Exemplary support for claims 19 and 20 is found on page 10, line 1, through page 11, line 31. Exemplary support for claim 21 is found on page 18, lines 18-21 and on page 10, line 1, through page 11, line 31. Exemplary support

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for claims 22 and 24 is found in the specification at page 8, line 4, and page 4, line 12.
Exemplary support for claims 23 and 25 is found in the specification on page 11, lines 21-25.
Exemplary support for claim 26 is found in the specification on page 15, line 36.

Applicant believes that the present application is now in condition for allowance.
Favorable consideration of the application as amended is respectfully requested.

CONCLUSION

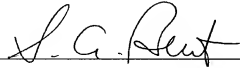
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Favorable consideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a
telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date November 20, 2002

By



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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.